

REMARKS

I. Status of the Subject Application

Claims 1-21 have been cancelled without disclaimer or prejudice. New Claims 22-41 are currently pending in the Subject Application. A Petition to Revive the Subject Application under 37 C.F.R. § 1.137(b) and the fee for the same are enclosed herewith.

II. Rejections Under 35 U.S.C. § 103(a)

In view of the cancellation of Claims 1-21, the Applicant respectfully submits that all of the 35 U.S.C. § 103(a) claim rejections in the Office Action are respectfully mooted.

III. New Claims 22-41

New Independent Claims 22, 29, 35, and 39

New Independent Claim 22 recites, among other things, a **modular sterilization assembly** comprising a **first module** for defining a sterile enclosure, including, an inlet port, an outlet port, a first barrier for covering the inlet port, and a second barrier for covering the outlet port, wherein the first and second barriers comprise a vapor permeable, microorganism impermeable material, and a second module configured to be **attached to and detached from** the first module, the second module comprising a sterilant and an opening, wherein the opening is configured to be placed in fluid communication with the inlet port. New Independent Claim 29 recites, among other things, a **modular sterilization assembly** comprising a first module for defining a sterile enclosure, the first module comprising an inlet port, an outlet port, a first barrier for covering the inlet port, and a second barrier for covering the outlet port, wherein the

first and second barriers comprise a vapor permeable, microorganism impermeable material, and a **second module configured to be engaged with the inlet port and the outlet port**, the second module comprising a sterilant, wherein the second module is configured to **circulate the sterilant into the first module and back into the second module**. New Independent Claim 35 recites, a **modular sterilization assembly**, comprising a first module configured to receive an item to be sterilized and a second module including a sterilant, wherein the first module is configured to be in fluid communication with the second module, and wherein **the second module is configured to be attached to and detached from the first module by at least one of a snap, a clip, and a hook and loop closure material**. New Independent Claim 39 recites, a method of sterilizing an item comprising receiving the item in a first module, sealing the first module with a vapor permeable, microorganism impermeable material, **removably attaching a second module to the first module**, wherein the second module includes a sterilant, flowing the sterilant into the first module, **flowing the sterilant back into the second module**, and detaching the first module from the second module while maintaining the item in a sterile condition within the first module.

Even though the 35 U.S.C. §103(a) claim rejections in the Office Action have been respectfully mooted by the Applicant's cancellation of Claims 1-21, the Applicant would like to address the two main references used in the rejection of the previous claims, namely, U.S. Patent No. 5,556,607 to Childers et al. ("Childers '607") and U.S. Patent No. 5,667,753 to Jacobs et al. ("Jacobs '753"). Childers '607 does not teach a **modular sterilization assembly**, as presently claimed, nor does Childers '607 teach flowing a sterilant back to the source of the sterilant. In fact, Childers '607 could not be used as a modular sterilization system in that the devices

disclosed by Childers '607, including source 14, are not modular, but instead are **part of a larger machine** including various components, such as vacuum pump 16 and catalytic converter 36. Furthermore, the sterilant of Childers '607 is **exhausted** through outlet 37 and exhaust outlet filter 38 and is **not flowed back to source 14** (Fig. 4). In addition, the Examiner states, and the Applicant agrees, that Childers '607 does not teach how to close the inlet and the outlet orifices after detaching the cassette from the source. Jacobs '753 does not remedy the deficiencies in Childers '607.

In one exemplary embodiment of Fig. 15 of the Subject Application, unlike the references cited above, a modular sterilization assembly is illustrated which can include a first module and a second module, wherein the first and second modules are removably attachable to each other. As illustrated, the first module can include an inlet port and an outlet port, wherein the inlet and outlet ports can be covered with a barrier comprised of a vapor permeable, microorganism impermeable material (Subject Application, para. [0076]). In such exemplary embodiments, one or more of the first and second modules can maintain a sterile environment therein when the modules are detached from each other. In addition, in one exemplary embodiment, sterilant can be circulated from the second module into the first module in order to sterilize an item in the first module. In such an embodiment, the sterilant can then be circulated back into the second module because of the operative alignments of the inlets and the outlets (Subject Application, Fig. 15). In still other exemplary embodiments, a second module can be attached to and detached from a first module by a snap, a clip, and/or a hook and loop closure material (Subject Application, para. [0076]). Such features can allow at least two modules to be easily attached to and detached from each other. In at least one embodiment, a detachable

second module can be re-used with a plurality of other first modules owing to the compartmentalized nature of the first and second modules (Subject Application, para. [0075]). For at least the reasons advanced above, Applicant respectfully submits that none of the references cited in the Office Action disclose the claimed features and, as a result, Applicant respectfully solicits the allowance of Independent Claims 21, 29, 35, and 39, and the claims depending respectively therefrom.


IV. Conclusion

Applicant respectfully submits that all of the new claims presented in the Subject Application are in condition for allowance. Applicant's present Amendment should not in any way be taken as acquiescence to any of the specific assertions, statements, etc., presented in the Office Action not explicitly addressed herein. Applicant reserves the right to specifically address all such assertions and statements in subsequent responses.

Applicant has made a diligent effort to properly respond to the Office Action and believes that the claims are in condition for allowance. If the Examiner has any remaining concerns, the Examiner is invited to contact the undersigned at the telephone number set forth below so that such concerns may be expeditiously addressed.

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Respectfully submitted,

A handwritten signature in black ink, reading "Christian M. Best". The signature is written in a cursive style with a horizontal line underneath it.

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